

ZENOL COOL- methyl salicylate poultice

Green Cross Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

methyl salicylate

l-menthol, dl-camphor, thymol, diphenhydramine hydrochloride, titanium oxide, kaolin, carboxymethylcellulose sodium, sodium polyacrylate, dried aluminum hydroxide gel, disodium edetate hydrate, gelatin, tartaric acid, polysorbate 80, sorbitan sesquioleate, nikazole TS-620, concentrated glycerin, borneol-p, rose incense, purified water, nonwoven fabric, polypropylene film

for the temporary relief of sore muscles, sprains, bruises, shoulder pain, arthralgia, backache, neuralgia, rheumatic pain and fracture pain


keep out or reach of the children


step 1: remove the colored protective sheet from the adhesive tape strip
step 2: attach the cotton side of Zenol medicated patch to the adhesive tape
step 3: remove the transparent protective film from the patch, and also the remainder of the colored protective sheet (the two strips with arrows on the side)
step 4: apply one or twice daily or as needed, to the affected skin surface
step 5: following the use, tightly close and fold the open end of the pack, in order to preserve the efficacy of the remaining patch

1. while skin irritations such as redness, eruption, or itchiness are uncommon, but if they would occur, discontinue usage and consult a physician or a pharmacist
2. if painful symptoms do not improve after application for several days, discontinue usage and consult with a physician or a pharmacist

for external use only

Fasten the laminated zip to keep the pack closed.





zenol

COOL TYPE

COMPOSITION: Each Sheet contains

Methyl salicylate(K,P)	160mg
dl - Menthol(K,P)	140mg
dl - Camphor(K,P)	80mg
Diphenhydramine HCl(K,P)	10mg

USAGE:
For the temporary relief of Sore Muscles, Sprains, Bruises, Shoulder Pain, Arthralgia, Backache, Neuralgia, Rheumatic Pain and Fracture Pain.

DIRECTIONS:
 Step 1: Remove the colored protective sheet from the adhesive tape strip.
 Step 2: Attach the cotton side of Zenol® medicated patch to the adhesive tape.
 Step 3: Remove the transparent protective film from the patch, and also the remainder of the colored protective sheet (the two strips with arrows on the side).
 Step 4: Apply once or twice daily or as needed, to the affected skin surface.
 Step 5: Following the use, tightly close and fold the open end of the pack, in order to preserve the efficacy of the remaining patch.


PROPERTIES:
 1. Zenol® Cool provides rapid, soothing pain relief and alleviates swelling, with a cool refreshing feeling owing to its cold-pack effect, while exerting potent anti-inflammatory and analgesic effects through the transdermal absorption of active ingredients.

2. Zenol® Cool holds a high moisture contents in its water-soluble polymer base, which enables the deep penetration of active ingredients into the affected area, and provides sustained effects through the continuous release of its moisture.
 3. Zenol® Cool with its special net-shaped gel base, has an excellent affinity to the skin, thus minimizing side effects such as contact dermatitis. It may be removed cleanly and easily, even from hairy skin surfaces, without pains.
 4. Due to its transdermal therapeutic system, Zenol® Cool can be used safely by the elderly and the feeble, as well as pregnant women, for whom oral therapy might be inappropriate.


PACKAGING:
Five Sheets, 5 1/2 x 3 1/2 inches in Aluminum Foil.

CAUTIONS:
 1. While skin irritations such as redness, eruption, or itchiness are uncommon, but if they would occur, discontinue usage and consult a physician or a pharmacist.
 2. If painful symptoms do not improve after application for several days, discontinue usage and consult with a physician or a pharmacist.

MANUFACTURED BY



GREEN CROSS CORP.



Goldenship Inc.

EST. 1980 (Green Cross, Inc.)

FCH-21-4507-2-1

ZENOL COOL

methyl salicylate poultice

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61476-100
Route of Administration	TRANSDERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	160 mg in 17 g

Inactive Ingredients

Ingredient Name	Strength
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
CAMPBOR (SYNTHETIC) (UNII: 5TJD82A1ET)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61476-100-01	17 g in 1 PATCH; Type 0: Not a Combination Product	11/23/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	11/23/2013	11/26/2023

Labeler - Green Cross Corp (687760561)

Establishment

Name	Address	ID/FEI	Business Operations
Green Cross Corp		689852033	manufacture(61476-100)

Revised: 11/2021

Green Cross Corp